# PHENYTOIN SODIUM

**Rx FENTIN** 50mg/mL
Solution for Injection (I.M/I.V)
**ANTIEPILEPTIC**

**FORMULATION:**
Each mL contains :
Phenytoin Sodium B.P .....50 mg

**PRODUCT DESCRIPTION:**
Fentin is used to control seizures (Convulsions) in the treatment of epilepsy. It is also used to prevent and treat seizures that occur during brain surgery. This medicine is in a class of medications called anti-convulsants.

**INDICATION:**
Used to control partial and generalised tonic-clonic seizures; for the treatment of status epilepticus and for the prevention and treatment of seizures associated with neurosurgery or severe traumatic injury to the head; for the treatment of trigeminal neuralgia.

**PHARMACOLOGY:**
Fentin (Phenytoin Sodium) is an anticonvulsant. The primary site of action appears to be the motor cortex where the spread of seizure activity is inhibited, Possibly by promoting sodium efflux from neurons, Fentin (Phenytoin Sodium) tends to stabilize the threshold against hyperexcitability caused by excessive stimulation or environmental changes capable of reducing membrane sodium gradient.This includes the reduction of post titanic potentiation at synapses,Loss of post-tetanic potentiation prevents cortical seizure foci from detonating adjacent cortical areas. Fentin (Phenytoin Sodium) reduces the maximal activity of brain stem centres responsible for the tonic phase of grand mal seizures.

**PHARMACOKINETICS:**
The plasma elimination half life of Fentin (Phenytoin Sodium) in humans averages 22 hours,with the range varying from 6 to 42 hours.Phenytoin is approximately 90% plasma protein bound. The liver is the major organ of elimination for Fentin (Phenytoin Sodium). Because this elimination route is readily saturable,small increases in dosage may produce substantial increases in plasma Phenytoin concentration as little as a 10% increase in daily dose may double or triple the steady state plasma Phenytoin concentration. In therapeutic doses, approximately 2% of Phenytoin is excreted. Unchanged via the kidneys.

**CONTRAINDICATIONS :**
- Hypersensitivity to the hydantoins
- Sinus bradycardia,SA block,second and third degree AV block and Adams Stockes Syndrome

**DOSAGE & ADMINISTRATION :**
Dosage should be individualized to provide maximum benefit. In some cases serum level determinations may be necessary for optimal dosage adjustments, the clinically effective serum level is usually 10 to 20 micrograms/ml.

**Adults:**

| Indication | Dosage | Administration |
|---|---|---|
| Status epilepticus / Seizure: | 10-15 mg/kg IV loading dose, followed by maintenance doses of 100 mg IV every 6-8 hours | Admix with a 50 ml of NS injection to a final concentration of 1-10 mg/ml.Infuse over 1 hour. Max rate of infusion is 50 mg/min |
| Antiarrhythmic: | 50-100 mg IV every 10-15 min as needed, max dose 15 mg/kg at a max rate of 50 mg/min | Admix with 50 ml of NS injection to a final concentration of 1-10 mg/ml. Infuse over 1 hour |

Pediatric:

| Indication | Dosage | Administration |
|---|---|---|
| Status epilepticus / Seizure: | 10-20 mg/kg IV loading dose, followed by maintenance doses of 5 mg/kg/day IV in 2-3 divided doses | Max rate of infusion is 0.5-3 mg/kg/min. Admix with 50 ml of Ns injection to a final concentration of 1-10 mg/ml. Infuse over 1 hour. |
| Antiarrhythmic: | 1.25 mg/kg every 5 minutes may repeat up to total loading dose of 15 mg/kg.Usual maintenance is 5-10 mg/kg/day in 2-3 divided doses. | Max rate of infusion is 0.5-3 mg/kg/min.Admix with 50 ml of Ns injection to a final concentration of 1-10 mg/ml.Infuse over 1 hour. |

**SIDE EFFECT :**
Toxic effects of Fentin (Phenytoin Sodium) related to the central nervous system typically occur at serum levels above 20 micrograms/milliliter and include nystagmus, ataxia, and lethargy. Blood dyscrasias, lymphoma, and cardiovascular toxicity (associated with parenteral administration), chorecoathetosis, encephalopathy, osteomalacia, nephrotoxicity, hepatotoxicity, and cutaneous reactions have also occurred.

**REPORTING OF SUSPECTED ADVERSE REACTIONS:**
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reactions is necessary.
Healthcare professionals are encouraged to report any suspected adverse reaction/s directly to the Importer/distributor and/or to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

**OVERDOSE & TREATMENT:**
The mean lethal dose in adults is estimated to be 2 to 5 grams. The lethal dose in children is not known. The initial signs are nystagmus, diplopia, ataxia, and dysarthria. Other signs are tremor, hyperflexia, lethargy, nausea, vomiting. The patient may become comatose and hypotensive. Death is due to respiratory and circulatory depression.
Attempts to relate serum levels of the drug to toxic effects have shown wide interpatient variation. Nystagmus on lateral gaze usually appears at 20mg/l and ataxia at 30mg/l. Dysarthria and lethargy appear when the serum concentration is above 40mg/l, although a serum concentration as high as 50mg/l has been reported without evidence of toxicity.
As much as 25 times the therapeutic dose, which resulted in a serum concentration of 100mg/l was taken with complete recovery. Irreversible cerebellar dysfunction and atrophy have been reported.
Treatment: There is no known antidote and treatment is symptomatic and supportive. Particular attention should be paid to circulatory and respiratory function and appropriate supportive measures employed.
Haemodialysis can be considered, since phenytoin is not completely bound to plasma proteins. Total exchange transfusion has been used in the treatment of severe intoxication in children.
In acute overdosage the possibility of the presence of other CNS depressants, including alcohol, should be borne in mind.
Phenytoin Injection is indicated for the control of status epilepticus of the tonic-clonic (grand mal) type and prevention and treatment of seizures occurring during or following neurosurgery and/or severe head injury.

**STORAGE:**
Store at temperatures not exceeding 30°C. Protect from light.

**CAUTION:**
Foods, Drugs, Devices, & Cosmetics Act prohibits dispensing without prescription.
**KEEP OUT OF REACH OF CHILDREN.**

FDA REGISTRATION NO. DRP-5568
DATE OF INITIAL OF AUTHORIZATION: 26 OCTOBER 2020
DATE OF REVISION OF PACKAGE INSERT: 16 SEPTEMBER 2021

**AVAILABILITY :**
USP Type 1 Amber Glass Ampoule x 1 mL ( Box of 5's)
USP Type 1 Amber Glass Ampoule x 2 mL ( Box of 5's)

Manufactured by:
GEOFMAN PHARMACEUTICALS
20/23, Korangi Industrial Area, Karachi, Pakistan.

Imported & Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave., Phase-III, BF Homes, Parañaque City.